

II AMENDMENT

In the Claims

Please cancel claims 1–25 and add new claims 26–45, as set forth below.

1. (Canceled) A method of making nanoparticles of a substantially water insoluble material comprising:

(a) preparing an emulsion system, having a dispersed phase and a continuous phase; the dispersed phase comprises globules containing said material within the continuous phase in the presence of a surfactant;

(b) diluting the emulsion by addition of a liquid that is miscible with the dispersed phase and the continuous phase, in an amount effective to dissociate said emulsion, thereby producing a uniform liquid phase in which nanoparticles of said material are suspended, said nanoparticles having an average particle size equal to or less than the globule size of said dispersed phase, and, optionally,

(c) separating said nanoparticles from said uniform liquid phase.

2. (Canceled) The method as claimed in claim 1 wherein the material is a therapeutic or diagnostic agent.

3. (Canceled) The method as claimed in claim 1, wherein the emulsion is diluted with the liquid that comprises the continuous phase.

4. (Canceled) The method as claimed in claim 1, wherein said nanoparticles have an average particle size less than about 200 nanometers.

5. (Canceled) The method as claimed in claim 1, wherein said nanoparticles have an average particle size less than about 50 nanometers.

6. (Canceled) The method as claimed in claim 5, wherein said therapeutic or diagnostic agent is substantially insoluble in water, and said emulsion is an oil-in-water emulsion or a water-in-oil emulsion.

7. (Canceled) The method as claimed in claim 1, wherein separation of said nanoparticles is effected by centrifugation.

8. (Canceled) The method as claimed in claim 1, wherein separation of said nanoparticles is effected by filtration.

9. (Canceled) The method as claimed in claim 1, wherein separation of said nanoparticles is effected by dialysis.

10. (Canceled) The method as claimed in claim 1, wherein the dispersed phase — continuous phase which constitutes said emulsion system (dispersed phase medium — continuous phase medium) is selected from the group of: triethyl citrate –water, dimethylsulfoxide – triglyceryl cabroate, and ethyl citrate-water.

11. (Canceled) The method as claimed in claim 1, wherein said therapeutic agent is selected from the group consisting of water insoluble anticancer drugs, antiviral drugs, immune-modulating agents, steroidal and non-steroidal anti-inflammatory agents, cardiovascular drugs and mixtures thereof.

12. (Canceled) The method as claimed in claim 10 wherein said therapeutic agent is selected from the group consisting of carmustine, methotrexate, carboplatin, azidothymidine, didanosine, dithrothritol, saquinavir, indinavir, retinovir, cyclosporine, hydrocortisone, prednisolone, ketoprofen, celecoxib, ibuprofen, methotrexate and mixtures thereof.

13. (Canceled) A substantially pure therapeutic or diagnostic agent, in the form of nanoparticles having an average particle size less than about 200 nanometers, produced by the method of claim 1.

14. (Canceled) The therapeutic agent, as claimed in claim 13, wherein the therapeutic agent is selected from the group of progesterone and testosterone.

15. (Canceled) The therapeutic agent, as claimed in claim 13, which also comprises a pharmaceutically acceptable carrier system.

16. (Canceled) The therapeutic agent as claimed in claim 12 which also comprises pharmaceutically acceptable adjuvants.

17. (Canceled) A diagnostic composition comprising the diagnostic agent nanoparticles, of claim 13, and a pharmaceutically acceptable carrier system.

18. (Canceled) A diagnostic composition comprising the diagnostic agent nanoparticles of claim 12 and pharmaceutically acceptable adjuvants.

19. (Canceled) A method of administering a therapeutic or diagnostic agent to targeted tissues or cells, comprising introducing into the targeted tissues or cells the agent of claim 13 in order to obtain selective accumulation of the nanoparticles of a therapeutic or diagnostic agent in the targeted site.

20. (Canceled) The method as claimed in claim 19 comprising the further step of injecting the therapeutic agent into targeted tissue or cells so that the nanoparticles of the therapeutic agent are slowly solubilized for sustained release into surrounding tissues or into plasma for circulation to other organs and tissues.

21. (Canceled) A method wherein the nanoparticles of therapeutic or diagnostic agent of claim 13 are administered orally.

22. (Canceled) The method as claimed in claim 19 wherein nanoparticles of the therapeutic or diagnostic agent are administered in the form of a suspension.

23. (Canceled) A method wherein the nanoparticles of the therapeutic or diagnostic agent of claim 13 are administered by injection into selected sites in the human body.

24. (Canceled) A method wherein the nanoparticles of the therapeutic or diagnostic agent of claim 13 are administered by surgical techniques.

25. (Canceled) A method wherein the nanoparticles of the therapeutic or diagnostic agent of claim 13 are applied topically.

26. (New) A method for making nanoparticles of a substantially water insoluble material selected from an antimicrobial agent, an antibacterial agent, an antifungal agent, an antiviral agent, an anti-HIV drug, an immunosuppressant, an anticancer agent and an antidiabetic agent, said method comprising the steps of:

(a) dissolving said material in a first liquid component of an emulsion system to form a solution;

(b) adding to the solution a second component of an emulsion system and an emulsifier to form a mixture and applying force to the mixture in order to transform the mixture into an emulsion comprising a continuous phase and a dispersed phase in which the continuous phase comprises the second component of

the emulsion system and the dispersed phase comprises globules of the material dissolved in the first liquid component, said globules having a diameter of between 10 and 200 nm; and

(c) treating the emulsion formed in step (b) with an additional amount of a liquid miscible with the first and second components, thereby transforming the emulsion into a liquid-solid suspension, whereby the solid phase comprises nanoparticles of the material.

27. (New) The method as claimed in claim 26, wherein the emulsion system comprises an alcohol having two to ten carbon atoms and a concentration in water of about 5% to about 95%.

28. (New) The method as claimed in claim 27, wherein the emulsion system comprises an alcohol having two to ten carbon atoms and a concentration in water of about 10% to about 70%.

29. (New) The method as claimed in claim 26, wherein the antidiabetic agent is selected from the group consisting of insulin, insulin salts and insulin complexes.

30. (New) The method as claimed in claim 29, wherein the insulin salt is insulin zinc.

31. (New) The method as claimed in claim 26, wherein the immunosuppressant is cyclosporine.

32. (New) The method as claimed in claim 26, wherein the anticancer agent is paclitaxel.

33. (New) The method as claimed in claim 26, wherein the antifungal agent is nystatin.

34. (New) The method as claimed in claim 26, wherein the antiviral agent is selected from the group consisting of acyclovir, ribarivan and interferons.

35. (New) The method as claimed in claim 26, wherein the antibacterial agent is selected from the group consisting of penicillin, cephalosporin, bacitracin, tetracycline, doxycycline, quinolones, clindamycin, and metronidazole.

36. (New) The method as claimed in claim 26, wherein the anti-HIV drug is selected from the group consisting of HIV protease inhibitor.

37. (New) The method as claimed in claim 36, wherein the HIV protease inhibitor is selected from the group consisting of saquinavir and zidovudine.

38. (New) A method for making nanoparticles of a substantially water insoluble material comprising a diagnostic agent, said method comprising the steps of :

(a) dissolving said material in a first liquid component of an emulsion system to form a solution;

(b) adding to the solution a second liquid component of an emulsion system and an emulsifier to form a mixture and applying force to the mixture in order to transform the mixture into an emulsion comprising a continuous phase and a dispersed phase in which the continuous phase comprises the second liquid component of the emulsion system, and the dispersed phase comprises globules of the material dissolved in the first liquid component, said globules having a diameter of between 10 and 200 nm; and

(c) treating the emulsion formed in step (b) with an additional amount of a liquid miscible with the first and second components, thereby transforming the emulsion into a liquid-solid suspension, whereby the solid phase comprises nanoparticles of the material.

39. (New) The method as claimed in claim 38, wherein the diagnostic agent is selected from the group of light imaging contrast materials for x-ray imaging, magnetic resonance imaging contrast agents and markers for diagnostic nuclear medicine used in scinetegraphy.

40. (New) The method as claimed in claim 39, wherein the light imaging contrast material is an iodepamide derivative of an iodinated material.

41. (New) The method as claimed in claim 39, wherein the magnetic resonance imaging contrast agent is a metal oxide.

42. (New) The method as claimed in claim 41, wherein the metal oxide is selected from the group consisting of Fe_3O_4 and Fe_2O_2 .

43. (New) The method as claimed in claim 39, wherein the marker for diagnostic nuclear medicine is selected from the group consisting of radio-labeled Technetium sulfur or Technetium oxide.

44. (New) A method for making nanoparticles of a substantially water insoluble material selected from the group consisting of pigment, photographing material, cosmetic ingredient, support material and toner material, said method comprising the steps of:

(a) dissolving said material in a first liquid component of an emulsion system to form a solution;

(b) adding to the solution a second liquid component of an emulsion system and an emulsifier to form a mixture and applying force to the mixture in order to transform the mixture into an emulsion comprising a continuous phase and a dispersed phase in which the continuous phase comprises the second liquid

component of the emulsion system, and the dispersed phase comprises globules of the material dissolved in the first liquid component, said globules having a diameter of between 10 and 200 nm; and

(c) treating the emulsion formed in step (b) with an additional amount of a liquid miscible with the first and second components, thereby transforming the emulsion into a liquid-solid suspension, whereby the solid phase comprises nanoparticles of the material.

45. (New) The method as claimed in claim 44, wherein the paint is an water-based paint.